

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Jessica R. DesNoyer, et al.

Serial No.: 10/750,312

Filed: 12/30/2003

For: STENT MANDREL SUPPORT AND
METHOD FOR COATING STENTS

Group Art Unit: 1792

Examiner: Lamb, Brenda A.

CONFIRMATION NO.: 1694

Mail Stop: Appeal Brief-Patents

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

REPLY BRIEF

Dear Sir:

Applicants' Reply Brief is filed in response to the Examiner's 10/1/2008 Supplemental Answer.

It is respectfully submitted that the Office's statements in support of the continued rejections of Applicants' claims under 35 U.S.C. § 103(a) are conclusory. The reasons given for the rejection do nothing more than describe the structure disclosed in each of the cited documents. As Applicants explain in their opening brief, never has an explicit reason been advanced for why one of ordinary skill in the art would have had a reason or motivation for mounting a stent on a mandrel as claimed.

For example, in its supplemental answer, the Office makes the following statement as to why Claim 23 would have been obvious over the combination of *Hattler* and *Rosenbluth*:

Hattler et al explicitly fails to teach the mandrel assembly in combination with a stent including a plurality of struts having abluminal and luminal surfaces in fluid communication through at least a pair of plurality of struts as set forth in newly amended claim 23. However, Rosenbluth teaches at column 10 line 53 to column 11 line 2 coating an expandable stent mounted on a mandrel and catheter assembly prior to its use. Therefore, it would have been obvious to arrange any conventional stent such as one taught by Applicant's Admitted Prior Art which has struts and structure within the scope of the claim on the Hattler et al mandrel and catheter assembly such that the member of the mandrel penetrates the longitudinal bore of the stent since Rosenbluth teaches mounting a stent on a catheter and mandrel assembly to enable one to coat the stent prior to its use.

Examiner's Supplemental Answer at page 8. Thus, the Office argues that since *Hattler* shows a structure falling within the scope of the claimed mandrel and *Rosenbluth* shows a stent on a balloon catheter, it would have been obvious to practice the invention of Claim 23. Applicants believe this rationale falls well short of setting out a *prima facie* case of obviousness because there is simply no rationale given as to why one of ordinary skill would have made such a combination. Indeed, it seems the Office has taken the following view of Section 103 law: if it is capable of being combined, then it would have been an obvious combination. According to the Supreme Court, the Office's basis for the rejection of Claim 23 is legally incorrect:

a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

KSR International Co. v. Teleflex Inc. et al., 127 S. Ct. 1727, 1741 (2007). It is recognized that this precedent also holds that there need not be a specific teaching, suggestion or motivation in the art. However, **"rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some**

articulated reasoning with some rational underpinning to support the legal conclusion of obviousness". *Id.* (citations omitted)(emphasis added). But the Office has made no effort to support its continued rejection of the claims based on an "articulated reasoning with some rationale underpinning to support the legal conclusion of obviousness." *Id.* Instead, it simply repeats, over and over again, the same conclusory statement.

A reason for finding a claim obvious may, for example, be based on applying a known technique to a device ready for improvement or selecting from a finite number of alternatives. *See Id.* at 1740-41. But the Office has not attempted to make its case based on one of these rationale. Although there is no obligation, it would have been helpful if the rejection was at least based on one of the Court-sanctioned rationale, which are listed in the MPEP. This case might then have been resolved by now and no need for this appeal.

A case for obviousness may be made by simply comparing what one of ordinary skill in the art would have concluded, based on his/her skill level, if faced with the same problem that had faced the inventors at the time of the invention. This rationale, however, would not apply to this case because the art of record contains no hint or suggestion that the problem identified by the Applicants was previously known. As set forth in the background of invention, the inventors realized there was a need to coat a stent to minimize coating defects yet not apply coating to the luminal surface of the stent. A solution to the problem is the structure recited in Claim 23. Interestingly, it appears the Office has assumed, without any proof, that the problem identified by Applicants was already known to one of ordinary skill in the art based on the frequent reference to Applicants' so-called admitted prior art.

If a conclusion of obviousness is premised on a solution to a problem that was not known at the time, then the conclusion was likely tainted by impermissible hindsight. Indeed, in view of the frequent reference to Applicants' specification, the suggested modification that would have rendered *Hattler's* device inoperable or, in the alternative, that *Hattler* teaches away from, *see*

Applicants Amended Appeal Brief at pages 9-11, it appears that hindsight played a key role in the Office's decision to reject Applicants' claims.

CONCLUSION

The Examiner has failed, as a matter of law, to set forth a case of obviousness under 35 U.S.C. § 103(a). Applicants therefore respectfully ask that the Board reverse the rejections of the claims and order the application to be passed to issue.

Date: Dec. 1, 2008

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Respectfully submitted,

A handwritten signature in black ink, appearing to read 'J. L. Reed', with a stylized flourish at the end.

James L. Reed

Reg. No. 43,877